

October 28, 2026

Grace R. Graham
Deputy Commissioner for Policy, Legislation,
and International Affairs
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Docket No. FDA-2026-N-9550: Advancing Development of Botanical Drug Products; Request for Information

Dear Deputy Commissioner Graham:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments on Docket No. FDA-2026-N-9550 for “[Advancing Development of Botanical Drug Products; Request for Information](#).” As a general principle, the AMA supports strengthening the ability of the U.S. Food and Drug Administration (FDA) to ensure the safety and efficacy of drug products for our patients, including botanicals, biologics, pharmaceuticals, and other drug classes.

The AMA supports a comprehensive, science-based focus when considering the broad range of FDA’s authority. An FDA decision to approve a new drug, withdraw a drug’s approval, or change the indications for its use must be based on sound scientific and medical evidence derived from high-quality clinical trials, real-world data (RWD) fit for regulatory purpose, and/or postmarket surveillance. The AMA believes that this information and data should be evaluated by the FDA, in consultation with its Advisory Committees and expert, independent extramural advisory bodies. Furthermore, any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to, or indications for, use of a drug unless the weight of the evidence from clinical trials, RWD fit for regulatory purpose, and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.

Before turning our comments to the RFI itself, the AMA also emphasizes that social and economic concerns and disputes should not be permitted to play a part in the FDA’s decision-making process as the FDA devises either general or product specific drug regulation on the basis of safety and efficacy. The AMA believes that political considerations or conflicts of interest should not be allowed to overrule scientific evidence in making policy decisions. These principles are particularly important in light of the growing use and public health harms related to a wide range of botanicals, including kratom, cannabis, kava, kanna, and other botanicals that are increasingly used by consumers for specious health claims made by their manufacturers or influencers. Although botanical substances were used historically, the formulations and synthesized derivatives of those products are much different today than their historical use.

To be clear, the AMA supports efforts to facilitate research on botanicals and other drug classes to help ensure the efficacy and safety of drug products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans. As botanical manufacturers create more products available in multiple forms (teas, powders, tablets, capsules, tinctures, topicals, gummies, oils, injections, etc.) with increasing potency, the AMA is deeply concerned that consumers often are the real-world guinea pigs who suffer tragic consequences, including dependence, use disorders, and death.

The AMA was pleased, therefore, to see the recent emergency scheduling action by the U.S. Drug Enforcement Administration (DEA) for three kratom-related compounds that, according to the [DEA order](#), “pose an imminent hazard to public safety: mitragynine pseudoindoxyl, commonly known as MGPI, and two synthetic compounds known as MGM-15 and MGM-16.” The AMA supports legislative and other efforts banning synthesized, purified, or derivative products from kratom for marketing, distribution, promotion, and sale, including but not limited to unregulated mitragynine along with the 7-hydroxymitragynine and MGM-15 market. Accordingly, the AMA has worked with multiple medical societies to support new laws protecting consumers from kratom and 7-OH products within their states.

We were particularly pleased to see the DEA rely on FDA’s assessment that “7-OH produces respiratory depression, physical dependence, and withdrawal symptoms characteristic of classical opioids, such as morphine, fentanyl, oxycodone, and hydrocodone.” Studies have found that “7-OH produces respiratory depression with more than threefold greater potency than morphine.” This is the type of safety assessment and information that the American public relies on FDA to provide to protect public health. Given the fact that FDA has reported that an estimated 1.7 million Americans aged 12 years and older used kratom in 2021, the AMA commends the FDA for its work to protect consumers from harmful botanicals, including kratom.

AMA policy with respect to support for cannabis research may also provide helpful considerations for FDA in its potential guidance for researchers. To start, the AMA supports adequate and well-controlled studies of cannabis and related cannabinoids, including derived psychoactive cannabis products (DPCPs) and hemp-derived intoxicating cannabinoids (HDICs), in patients who have serious conditions for which preclinical, anecdotal, or animal model evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease. Additionally, we encourage expanded research into the therapeutic uses of cannabis in special populations like older adults, such as for managing agitation in individuals with cognitive impairment, weighing the information on efficacy with potential adverse effects. While the AMA believes that cannabis is a dangerous drug and as such is a serious public health concern, we believe there is a clear role for the National Institutes of Health (NIH), the DEA, and the FDA to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. Therefore, the AMA supports the following:

- Disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation;
- Sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; and
- Confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.

Even as the AMA supports cannabis-related research, simultaneous efforts must be made to support research to determine the consequences of long-term cannabis use, as well as the use of DPCPs and HDICs, especially among youth, adolescents, and women who are pregnant or breastfeeding. The FDA approval process for drugs containing cannabis or other botanicals should not be short-circuited or circumvented merely because of anecdotal support or growing public use. Manufacturers increasingly tout their products as “botanical” while—as the DEA emergency scheduling action demonstrates—their products are incredibly dangerous, synthesized drugs that pose imminent public health threats to consumers.

While the AMA supports innovation in drug design and development, we also urge extreme caution about deviating from known and widely accepted scientific and clinical standards for testing safety and efficacy. In a time where social influencers, rogue telehealth companies, and “botanical health” companies ply consumers with promises of cures from “natural” products, the AMA urges FDA to continue to rely on time-tested quality and research standards that have protected American consumers for decades. The lack of standardization by manufacturers for consumer products has resulted in a dangerous, buyer-beware marketplace. Whether it is a product containing kratom, cannabis, or other botanicals, the AMA strongly recommends that the substance—and its derivatives—be regulated by the FDA, and that its safety and efficacy be determined through clinical trials before it can be marketed or prescribed as treatment for any condition.

Thank you for your consideration. Please reach out to me directly at 312-464-5288 or John.Whyte@ama-assn.org if you have questions or need further information.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Whyte', with a stylized, cursive script.

John Whyte, MD, MPH